IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC. and MAYNE PHARMA INTERNATIONAL PTY LTD.,	)	
Plaintiffs,	)	C.A. No. 13-2002-GMS
v.	)	**JURY TRIAL DEMANDED**
FOREST LABORATORIES, INC.,	)	
Defendant.	)	

PLAINTIFFS' OPPOSITION TO DEFENDANT'S
MOTION FOR JUDGMENT ON THE PLEADINGS

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I. INTRODUCTION

Plaintiffs, Teva Pharmaceuticals USA, Inc. and Mayne Pharma International Pty Ltd,. (collectively "Teva and Mayne" or "Plaintiffs") oppose Defendant, Forest Laboratories, Inc.'s, ("Forest's") Motion for Judgment on the Pleadings Pursuant to Fed. R. Civ. P. 12(c) (herein the "Motion to Dismiss"). Forest's Motion wrongly casts this case as an off-label method of use Hatch Waxman ANDA case. It is not. Contrary to Forest's Motion, the claims of the '000 patent are not directed to methods of "treating wind-up." Indeed, that phrase does not even appear in the asserted patent.

Instead, certain claims of the asserted patent, U.S. Patent 6,194,000 (herein the "'000 Patent") are directed to a method of preparing an analgesic composition containing an NMDA receptor antagonist, such as memantine. D.I. 1-1, '000 Patent, at *e.g.*, claim 1. Other claims are directed to methods of treatment of certain conditions, including Alzheimer's Disease, using memantine. *Id.* at, e.g., claim 12.

Forest launched the *branded* drug, Namenda XR, in the United States in June 2013. D.I. 1, Complaint, ¶ 7. Namenda XR indisputably contains an active ingredient claimed in the '000 patent, memantine, and it is indisputably approved for a method of use claimed in the '000 patent, the treatment of Alzheimer's Disease. D.I. 9-1, Prescribing Information for Namenda XR, at § 1, Indications and Usage. As Forest correctly states, the claims of the '000 patent recite that the claimed composition contains memantine in "sufficient amounts to diminish or abolish wind-up." *Id.* Forest ignores, however, that both the specification and claims recite that such an amount is in the range of 1 to 5000 mg/day, typically 1 to 1000 mg/day of memantine. D.I. 1-1, '000 Patent, col. 2, lines 39-42, claims 13 and 14, and that Namenda XR indisputably contains an amount of memantine -- 28 mg/day -- that falls squarely within that range. D.I. 9-1, Prescribing

Information, Sections 2 and 3. Moreover, Forest further ignores that in its own patents, which are listed in the Orange Book as covering Namenda XR, it has repeatedly represented to the Unites States Patent Office that compositions containing memantine at the dosage found in Namenda XR are effective in treating not just Alzheimer's Disease, but also pain. It is inconsistent for Forest to now suggest to this Court that such compositions have no effect on pain.

In short, the Complaint properly pleads that Forest has infringed and continues to *directly* infringe one or more claims of the '000 patent in violation of 35 U.S.C. § 271(a) and 271(g) by preparing a composition using the method claimed in the '000 patent. D.I. 1, Complaint at ¶¶ 17-21. The Complaint also properly pleads that Forest is actively inducing and contributing to direct infringement of the '000 patent by doctors who prescribe Namenda XR, *for its approved indication* -- treatment of Alzheimer's Disease -- in violation of 35 U.S.C. § 271(b) and (c). *Id*., ¶¶ 22-34. Because the Complaint states plausible claims for direct and indirect infringement, Forest's Motion should be denied.

II. NATURE AND STAGE OF THE PROCEEDINGS

The Complaint was filed on December 5, 2013. D.I. 1. Forest filed its Answer and Counterclaim on April 4, 2014. D.I. 9. Forest's affirmative defenses and counterclaim are silent as to the absence of any limitation of the '000 patent other than the "wind-up" limitation, and Forest does not assert that the '000 patent fails to meet the novelty and non-obviousness requirements of 35 U.S.C. § 102 and 103. Rather, Forest's Counterclaim seeks only a declaration of non-infringement based only on the alleged absence of the "wind-up" limitation in Namenda XR. *Id.* at Counterclaim. In support of its Counterclaim, Forest attached several publications discussing the diagnostic criteria for Alzheimer's Disease, as well as the Namenda

XR package insert (i.e., the Label or Prescribing Information), which it apparently asserts are relevant to the question of infringement. On April 28, 2014, Plaintiffs filed their reply to Forest's Counterclaim, denying that Forest is entitled to judgment of non-infringement. D.I. 12. Without further communication, Forest filed the instant Motion to Dismiss. Forest's Motion to Dismiss correctly acknowledges that this case is in its very early stages, that no discovery has been conducted and no case schedule has been set by the Court.

III. SUMMARY OF ARGUMENT

Forest's Motion should be denied for at least three reasons. First, Forest's Motion is based on the erroneous premise that the claims of the '000 patent are directed to "treating wind-up." Indeed the phrase "treating wind-up" or "treatment of wind-up" appears no less than ***19 times*** throughout Forest's Memorandum. Importantly, however, the phrase "treating wind-up" or "treatment of wind-up" appears exactly ***zero times*** in the '000 patent. It is not in the claims, or even the specification. Forest cannot avoid infringement by asserting its product lacks a claim limitation which is itself lacking from the claims. Forest's attempt to rewrite the claims to require an off-label method of use should be rejected.

Secondly, Forest's Motion asks the Court to engage in premature claim construction as to the meaning of the claim limitation "sufficient amounts to diminish or abolish wind-up," and premature fact finding as to whether Namenda XR contains such an amount. Forest's Motion is premised on the erroneous assertion that the claim limitation "sufficient amounts to diminish or abolish wind-up," must be construed to mean an amount that has been shown in controlled clinical trials to be efficacious in "treating wind-up."[1] Forest's Motion is further premised on the erroneous assertion that merely because the word "wind-up" does not appear in the Namenda XR

[1] As will be shown at an *appropriate* time, Forest's construction is at odds with the specification and prosecution history of the '000 patent, as well as the law of claim construction.

label, as a matter of law, Namenda XR necessarily lacks memantine in "sufficient amounts to diminish or abolish wind-up." Forest's logic is deeply flawed. The claims are directed to methods of, for example, treating Alzheimer's disease with memantine (claim 12) and preparing an analgesic composition containing memantine (claims 1), *not* methods of "treating wind-up." Moreover, the Court need not, and indeed *should not*, engage in claim construction or fact finding on a Rule 12(c) motion. Nor may the Court draw inferences adverse to Plaintiffs. Plaintiffs are entitled to the opportunity to present evidence that Namenda XR, in fact, contains memantine in sufficient amounts to diminish or abolish wind-up and that, by making and instructing doctors to prescribe Namenda XR, Forest directly and indirectly infringes the claims of the '000 patent. The Court, at this stage, has no intrinsic or extrinsic evidence that may be important in analyzing the meaning of the claims, or whether Namenda XR meets them. Taking the allegations in the Complaint as true, and construing all disputed contentions in Plaintiffs' favor, as the Court must at this stage of proceedings, Forest's Motion should be denied.

Third, the legal authorities which provide the foundation for Forest's Motion strongly support *denying*, rather than granting, Forest's Motion. Forest asserts that the Federal Circuit's decisions in *Warner-Lambert Co. v. Apotex Corp.,* 316 F.3d 1348 (Fed. Cir. 2003) and *Allergan, Inc. v. Alcon Labs., Inc*., 324 F.3d 1322 (Fed. Cir. 2003), support dismissal. However, both of those cases were decided at the *summary judgment* stage, after the parties had the opportunity to develop a full record and the Court had conducted claim construction. As such, those cases do not support the relief Forest seeks here.

Moreover, unlike the Complaint here, none of Forest's cited cases addressed claims for direct infringement under § 271(a) and (g), inducement of infringement under 35 U.S.C. § 271(b) or contributory infringement under § 271(c) for an *approved* drug. Rather, in the cases Forest

relies upon, the defendant had committed only an "artificial" act of infringement -- the filing of an ANDA -- giving rise to a claim of inducement of infringement under 35 U.S.C. § 271(e)(2). None of the cases relied upon by Forest even discuss direct infringement or contributory infringement. By contrast, here, Forest is actively marketing the *approved* accused drug, Namenda XR, and its label therefore is not dispositive. Indeed, as Forest admits in footnote 1 of its Memorandum, "a doctor 'may prescribe an approved drug for any use consistent with acceptable medical practice." D.I. 14, p. 10, note 1. Forest's inapposite case law provides no authority on which to dismiss any count of the Complaint.

To the contrary, as discussed below, it is very well settled that a complaint, such as the Complaint here, that comports with Form 18 of the Federal Rules of Civil Procedures, is sufficient to plead a claim for direct infringement. As to inducement of infringement and contributory infringement, the Complaint contains a level of factual detail which has repeatedly been found sufficient by courts within the Third Circuit to withstand a motion to dismiss. Forest does not argue otherwise.

In sum, Forest's Motion should be denied because it asks this Court, at the pleadings stage, to draw inferences adverse to Plaintiffs and embrace Forest's mischaracterization of the '000 patent, without regard for the actual claim language, the facts, the rules of procedure, or the applicable case law.

IV. STATEMENT OF FACTS

The '000 patent issued on February 27, 2001 and is concerned with compositions containing N-methyl-D-aspartate (NMDA) receptor antagonists and their use. [2] In addition to

[2] In addition to the asserted patent, which is attached to the Complaint, the following Statement of Facts also refers to public records of the United States District Court for the District of Delaware and the United States Patent Office. The Court may take judicial notice of the

treating pain, the '000 patent teaches that by blocking NMDA receptors, NMDA receptor antagonists are also effective in the treatment of Alzheimer's disease. D.I. 1-1, '000 patent, col. 1, lines 57-63. Memantine (the active ingredient in Namenda XR) is identified as a preferred NMDA receptor antagonist. *Id*. col., 2, line 33. Claim 1 is directed to a method of preparing an analgesic pharmaceutical composition that provides sustained release of an NMDA receptor antagonist and immediate release of an NMDA receptor antagonist, the immediate release form and sustained release form being present in sufficient amounts to diminish or abolish wind-up. *Id*. col. 16, lines 46-61. Claim 12 is directed to methods of treating various conditions, including Alzheimer's disease, by administering an analgesic composition that provides sustained release of an NMDA receptor antagonist and immediate release of an NMDA receptor antagonist, the immediate release form and sustained release form being present in sufficient amounts to diminish or abolish wind-up. *Id*. col. 12, lines 45-57. With respect to the term "wind-up," during prosecution of the '000 patent, applicants explained to the examiner that "[t]he term 'wind up' relates to an increase in output to a repeated constant input or stimulus." Exh. A, June 14, 1999 Office Action Response at p. 11. In response to the examiner's indefiniteness rejection

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foregoing documents. *See* Fed. R. Evid. 201(b); *Kos Pharms., Inc. v. Andrx Corp*., 369 F.3d 700, 705 n.5 (3d Cir. 2004) ("According to records available on the PTO website, a Notice of Allowance for the ALTOPREV mark was issued on February 24, 2004. We may take judicial notice of such public records."). The Court may also consider the foregoing documents without converting Forest's Rule 12(c) Motion to a summary judgment motion. *See e.g., Southmark Prime Plus, L.P. v. Falzone*, 776 F. Supp. 888, 891-892 (D. Del. 1991) ("on a motion for judgment on the pleadings, as with motions to dismiss pursuant to Rule 12(b), the Court is not strictly limited to the facts addressed in the pleadings; the Court may take judicial notice of additional facts where appropriate. . . . Despite the language of Rule 12(c), the consideration of the judicially noticed facts does not convert the motion into a Rule 56 motion for summary judgment. It is only when the Court goes beyond the pleadings and judicially noticed facts that the Court must convert the motion and give both sides notice and an opportunity to supplement the factual record."). Plaintiffs respectfully request that the Court take judicial notice of the records of the Patent Office and the United States District Court for the District of Delaware cited herein, and not convert Forest's Motion to a motion for summary judgment.

pursuant to 35 U.S.C. § 112, applicants argued the Examiner was "in error that the degree of relief must be quantified." *Id.* Thereafter, the examiner permitted the '000 patent to issue.

Shortly after the Complaint in this action was filed, the defendant here, Forest, filed a separate lawsuit against one of the plaintiffs here, Teva, in this District, for infringement of a number of patents which Forest listed in the Orange Book as covering Namenda XR. *See Forest Labs, Inc, et al. v. Teva Pharmaceuticals, Inc., et al.,* D. Del. Case No. 1:14 cv 00121-UNA (herein the "Namenda XR ANDA Litigation"). Therein, Forest asserts that Teva's filing of an ANDA seeking approval to market a generic version of Namenda XR infringes Forest's Orange Book listed patents. *Id*., D.I. 1 Complaint at ¶ 35. The patents asserted by Forest include: United States Patent Nos. 5,061,703, as corrected and reexamined; 8,039,009 ("the '009 patent"); 8,168,209, as corrected ("the '209 patent"); 8,173,708 ("the 708 patent"); 8,283,379 ("the '379 patent"); 8,329,752 ("the 752 patent"); 8,362,085 ("the '085 patent"); and 8,598,233 ("the '233 patent"). *Id.* at ¶ 12. By listing the foregoing patents in the Orange Book, Forest asserts that they claim Namenda XR or the use thereof. *See* 21 U.S.C. § 355(b)(1)(g).

Forest's '009 patent claims priority to a provisional patent application filed in 2004, three years after the '000 patent (the asserted patent here) issued. The '000 patent is cited as prior art to, and discussed in the Background Section of, the '009 patent. *See* Exh. B hereto, '009 patent, cover page; col. 2, lines 55-64. Thus, there can be no question Forest has been aware of the '000 patent since at least 2004, and was aware of it when it developed Namenda XR. The '009 patent is directed to a "method for treating Alzheimer's disease comprising once daily administration of a modified release solid oral dosage form comprising 28 mg ±5% of memantine." *Id*. at claim 1. The specification of the '009 patent states that "[a]pproval of memantine is currently sought for the indication of neuropathic pain (wherein memantine has demonstrated activity in in vitro

models) . . .” *Id*. col. 6, lines 2-4. The ‘009 patent further states that the “memantine formulations of the invention are suitable for the treatment of . . . neuropathic pain” and that “[o]f particular interest is the ability to provide uninterrupted pain relief.” *Id*., col. 9, lines 48-61.

The other patents asserted by Forest to cover Namenda XR contain similar or even stronger admissions regarding the efficacy of the disclosed memantine compositions to treat not just Alzheimer’s Disease, but also other central nervous system related conditions, such as pain. *See e.g.,* Exh. C, underlined copy of ‘708 patent at col. 6, lines 5-32 (“the administration of the compositions described herein at therapeutically effective doses from the initiation of therapy enables . . . . the treatment of more acute disorders such as pain . . . . The compositions of the present invention are also useful to treat, prevent, or reduce conditions associated with such activities in any subject having or at risk of having a such condition. Exemplary conditions include . . . pain syndromes, . .[and] . . . dementias, . . .”). Indeed, the Orange Book patents for Namenda XR not just disclose, but also *claim*, methods of treating both Alzheimer’s disease *and pain,* using a dosage form containing 28 mg of memantine -- *the precise amount contained in Namenda XR*. *Compare* D.I. 9-1, Prescribing Information, § 2 *to* Exh. C, ‘085 patent, col. 37-38, claims 1, 5, 7 and 11. For the Court’s convenience, attached as Exhibit C hereto are copies of the patents asserted by Forest in the Namenda XR ANDA Litigation, wherein statements regarding the efficacy of the disclosed compositions for the treatment of pain have been underlined.

In addition, since 2005, Forest has sought patent protection for a composition comprising an immediate release component containing memantine combined with a sustained release component containing memantine, and a method of treatment of Alzheimer’s Disease or neuropathic pain, using such a composition. *See* Exh. D, U.S. Publication No. 2013-0302430,

claims 51 and 59 (claiming priority to Application No. 11/424,024 and to Provisional application No. 60/691,512, filed on Jun. 16, 2005). To date, however, Forest has failed to convince the Patent Office that its composition is distinct from that disclosed in the '000 patent. *See* Exh. E, February 23, 2012 Office Action issued as to Application No. 11/424,024 (rejecting Forest's claims in view of '000 patent).

In sum, in the public records of the Patent Office, Forest admits that it has been aware of the '000 patent since at least 2004, and that a composition containing 28 mg of memantine, such as Namenda XR, is suitable for both the treatment of pain and the treatment of Alzheimer's disease.[3] Moreover, to this day, Forest is still attempting to obtain patents with claim scope that overlaps with the '000 patent. *See* Exh. D, U.S. Publication No. 2013-0302430. In view of its statements to the Patent Office, it is inconsistent for Forest to now suggest to this Court that Namenda XR has no effect on pain.

V. ARGUMENT

A. Applicable Legal Standard.

Pursuant to Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings "[a]fter the pleadings are closed--but early enough not to delay trial. ..." Fed. R. Civ. P. 12(c). Courts evaluating Rule 12(c) motions may grant judgment on the pleadings if "'the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law.'" *Rosenau v. Unifund Corp*., 539 F.3d 218, 221 (3d Cir. 2008) (quoting *Jablonski v. Pan Am. World Airways, Inc.,* 863 F.2d 289, 290-91 (3d Cir. 1988)).

[3] The fact Forest gained allowance of its Orange Book patents over the '000 patent has no bearing on whether Namenda XR infringes the '000 patent. *See e.g., Ariad Pharms., Inc. v. Eli Lilly & Co*., 598 F.3d 1336, 1365 (Fed. Cir. 2010) ("The Supreme Court has long acknowledged the 'well established' rule that 'an improver cannot appropriate the basic patent of another and that the improver without a license is an infringer and may be sued as such.'") (*citing Temco Elec. Motor Co. v. Apco Mfg. Co*., 275 U.S. 319, 328 (1928)).

Rule 12(c) motions are reviewed under the same standards as motions to dismiss filed pursuant to Fed. R. Civ. P. 12(b)(6). *Novartis Pharms v. Actavis, Inc*., 2012 U.S. Dist. LEXIS 176445, C.A. No. 12-366-RGA-CJB (D. Del. Dec. 5, 2012). Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis,* 372 F.3d 218, 223 (3d Cir. 2004). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.,* 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted). Thus, the Court may grant such a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.,* 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted). At bottom, "[t]he complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element" of a plaintiff's claim. *Wilkerson v. New Media Tech. Charter Sch. Inc.,* 522 F.3d 315, 322 (3d Cir. 2008) (internal quotation marks omitted).

B. Plaintiffs' Allegations of Direct Infringement By Forest Comply With Form 18 and Are Therefore Properly Pled.

Forest's Motion fails to even mention the central holding in *In re Bill of Lading Transmission & Processing System Patent Litigation*, 681 F.3d 1323, 1333 (Fed. Cir. 2012), that Form 18 of the Appendix of Forms to the Federal Rules of Civil Procedure meets the pleading requirements of Rule 8(a)(2). Forest also fails to inform this Court that the rule of sufficiency of Form 18 for pleading direct infringement has been adhered to *without fail* by district courts in the Third Circuit since *In re Bill of Lading*. *See e.g., EON Corp. IP Holdings LLC v. FLO TV Inc.,* 802 F. Supp. 2d 527, 532 (D. Del. 2011); *Mallinckrodt Inc. v. E-Z-EM Inc.*, 670 F. Supp. 2d 349,

353 (D. Del. 2009); *S.O.I.T.E.C. Silicon on Insulator Techs., S.A. v. MEMC Elec. Materials, Inc.,* C.A. No. 08-292-SLR, 2009 U.S. Dist. LEXIS 13155, at *2 (D. Del. Feb. 20, 2009).

The Complaint's allegations of direct infringement exceed what is required by Form 18, and Forest has not argued otherwise. In particular, the Complaint complies with Form 18, because it contains: (1) an allegation of jurisdiction (D.I. 1 at ¶¶ 5-8); (2) a statement that Plaintiffs own the patent in suit (*id.* at ¶ 1), (3) a statement that Forest has been infringing the patent in suit by making, offering to sell, selling and/or importing Namenda XR (*id.* at ¶¶ 14, 15, and 18); (4) a statement that Forest is aware of Plaintiff's patent rights (*id.* at 19, 23, and 29); and (5) a demand for an injunction and damages (*id*. at page 6, Prayer for Relief). *See* Fed. R. Civ. P. Form 18 (2014); Fed. R. Civ. P. 84 ("the forms in the Appendix suffice under these rules and illustrate the simplicity and brevity that these rules contemplate"). These allegations are sufficient to state a claim for direct infringement. No further detail is required.

Forest's argument appears to be that the Complaint fails to plead direct infringement because it does not expressly recite the claim limitation "wind-up," or allege that Namenda XR is efficacious for the "treatment of wind-up." However, contrary to Forest's contention, "a plaintiff in a patent infringement suit is not required to specifically include each element of the claims of the asserted patent," or "even identify which claims it asserts are being infringed." *In re Bill of Lading, 681 F.3d at 1335; see also e.g., K-Tech Telecomms., Inc. v. Time Warner Cable, Inc.,* 714 F.3d 1277, 1283-1284 (Fed. Cir. 2013) *(quoting McZeal v. Sprint Nextel Corp.,* 501 F.3d 1354, 1357 (Fed. Cir. 2007)); *Xpoint Techs.,v. Microsoft Corp.,* 730 F. Supp. 2d 349, 353 (D. Del. 2010) ("A plaintiff is not required . . . to describe how the allegedly infringing products work."); see *also Elen IP LLC v. Arvin Meritor, Inc.,* Case No. C11-140-RSM, 2011 U.S. Dist LEXIS 92563, at *9 (W.D. Wash, Aug. 18, 2011) (rejecting defendant's argument that complaint

should be dismissed because it did not allege all claim limitations were found in defendant's product). Forest's attempt to require, at this stage, a limitation-by-limitation description of how Namenda XR meets each patent claim element should be rejected.

C. Forest's Motion Improperly Requests That The Court Embrace Forest's Construction Of Claim Terms, And Make Factual Determinations As To Whether Namenda XR Meets Those Terms, At The Pleading Stage.

It is well settled that resolution of patent infringement allegations involves a two step process: "[t]he court must first interpret the claim and determine the scope and the meaning of the asserted patent claims, and then compare the properly construed claims to the allegedly infringing device." *Liquid Dynamics Corp. v. Vaughan Co., Inc*., 355 F.3d 1361, 1367 (Fed. Cir. 2004) (citation omitted). Judges in and outside this District have repeatedly held that if a court is required to construe the meaning of claim terms and perform an infringement analysis in order to resolve a motion to dismiss or a motion for judgment on the pleadings, the motion should be denied, because this type of analysis is inappropriate at the pleading stage. *See, e.g., Novartis,* 2012 U.S. Dist. LEXIS 176445, at *21; *Deston Therapeutics LLC v. Trigen Labs. Inc.,* 723 F. Supp. 2d 665, 670 (D. Del. 2010). "These courts have reasoned that it is unsuitable to engage in such an inquiry at the pleading stage, because claim construction can be illuminated by the consideration of extrinsic evidence--evidence that is often not before the court at that stage." *Novartis,* 2012 U.S. Dist LEXIS 176445, at *24; *Deston Therapeutics,* 723 F. Supp. 2d at 670. They also note that a claim construction analysis at the pleading stage does not benefit from the procedures (including an exchange of discovery documents relating to infringement, the exchange of proposed constructions and claim construction briefing) that precede a *Markman* hearing pursuant to typical scheduling orders in this District. *See, e.g., Deston Therapeutics,* 723 F. Supp. 2d at 670. Thus, the Court should refrain from granting a motion to dismiss, if it

effectively asks the Court to "embrace its characterization of the patent[]". *Novartis*, 2012 U.S. Dist LEXIS 176445, at *26 (quoting *Butamax Advanced Biofuels LLC v. Gevo, Inc.* C.A. No. 11-54-SLR, 2012 U.S. Dist LEXIS 86215 (D. Del. June 21, 2012).

Here, Forest argues that the Complaint fails to plead direct infringement because the Prescribing Information for Namenda XR "does not include treatment of wind-up or pain of any kind in the Indications and Usage section, does not include any information relating to use of Namenda XR to treat wind-up or pain of any kind, and does not even include the word 'wind-up.'" D.I. 14, at p. 13. One problem with Forest's argument is that, as discussed above, the phrase "treatment of wind-up" does not appear anywhere in the '000 patent, much less in the claims. Instead, as indicated above, the plain language of the claims is directed to, *inter alia,* treatment of Alzheimer's Disease (D.I. 1-1, '000 Patent, at *e.g.*, claim 12), *not* "treatment of wind-up." Accepting Forest's argument would require the Court to improperly construe the phrase "sufficient amounts to diminish or abolish wind-up" to require a method for the "treatment of wind-up," and to make a further determination that the mere absence of the word "wind-up" in Forest's label necessitates the factual conclusion that Namenda XR lacks such an amount. That is improper on a Rule 12(c) motion to dismiss.

Moreover, Forest ignores that both the specification and claims recite that the formulations of the invention may contain an amount in the range of 1 to 5000 mg/day, typically 1 to 1000 mg/day. *Id*., col. 2, lines 39-42, claims 13 and 14. The maintenance dose of Namenda XR is 28 mg/day, which indisputably falls squarely within the foregoing range. In addition, in its own patents covering Namenda XR, Forest has repeatedly stated to the Patent Office that Namenda XR is suitable for the treatment of pain. *See supra*, at p. 7-9; Exhibit C (underlined copies of Orange Book patents for Namenda XR). It is inconsistent for Forest to now tell this

Court otherwise. Drawing all inferences in Plaintiffs' favor, as the Court must in deciding a Rule 12(c) Motion, Namenda XR contains memantine in "sufficient amounts to diminish or abolish wind-up." Dismissal is therefore improper.

In sum, the mere absence of the phrase "wind-up" from the Prescribing Information for Namenda XR is not relevant, and certainly not dispositive, as to whether the Complaint pleads claims for infringement. The Court should not embrace Forest's revision of the claims to dismiss the Complaint, without first allowing the appropriate development of the record. Forest's Motion should be denied.

D. Plaintiffs Have Properly Pleaded Inducement of Infringement Under 35 U.S.C. § 271(b).

Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Four elements are required to state a claim for induced infringement: "(1) there was direct infringement by the induced party; (2) the inducer had knowledge of the asserted patents; (3) the inducer "possessed specific intent [and] not merely . . . knowledge of the acts alleged" to induce; and (4) there was active inducement of the direct infringer. *See Bel-Fuse Inc. v. Molex Inc.,* C.A. No. 13-2566, 2014 U.S. Dist LEXIS 81954, at *16-17 (D. N.J. June 16, 2014); *Medtronic Vascular, Inc. v. Boston Scientific Corp*., 348 F. Supp. 2d 316, 323 (D. Del. 2004); *Walker Digital, LLC v. Facebook, Inc.,* 852 F. Supp. 2d 559, 563 (D. Del. 2012).

The Complaint pleads all required elements of inducement. With respect to direct infringement, the Complaint states as follows: "doctors prescribing or administering Namenda XR® according to the 'Indications and Usage' section of the Namenda XR® current package insert will be using Namenda XR® in a manner that directly infringes one or more claims of the '000 patent." D.I. 1, at ¶ 22.

With respect to whether Forest had the requisite knowledge of the patent in suit, and intent to induce infringement, the Complaint states as follows: "*aware of Plaintiffs' patent rights*, Defendant has actively and *knowingly* induced and is continuing to induce infringement under 35 U.S.C. § 271(b) of the '000 patent by *intentionally* encouraging the administration of Namenda XR® for the treatment of medical conditions including Alzheimer's Disease." *Id*., ¶ 23 (emphasis added). The Complaint further alleges that "Defendant's actions constitute knowing and willful infringement of the '000 patent." *Id*., ¶ 24. Similar allegations have repeatedly been found sufficient by courts within the Third Circuit and elsewhere. *See e.g., Walker Digital,* 852 F. Supp. 2d at 563; *Telecomm Innovations, LLC v. Ricoh Co., Ltd*., 966 F. Supp. 2d 390, 395 (D. Del. 2013); *See Bel-Fuse Inc.,* 2014 U.S. Dist LEXIS 81954, at *16-17.

Notably, Forest has not even argued that the Complaint fails to satisfy the elements for a claim of induced infringement. Instead, Forest erroneously tries spins this case as an "off label use" case, sprinkling the phrase "off label" throughout its argument. Forest's argument ignores the language of claims. For example, claim 12 of the '000 patent is directed to a "method for the treatment of . . . Alzheimer's disease." Forest's Prescribing Information instructs doctors to prescribe Namenda XR for the "treatment of moderate to severe dementia of the Alzheimer's type." D.I. 9-1, Indications and Usage. Forest previously submitted a sworn declaration in another civil action in this District stating as follows:

> Beginning in 1987, the Diagnostic and Statistical Manual of Mental Disorders ("DSM") set forth the diagnostic criteria for "dementia of the Alzheimer's type." The term "dementia of the Alzheimer's type" has been used interchangeable by persons in the field with the term "Alzheimer's disease" since this time, at least.

See Exh. F, Declaration of Steven H. Ferris, PH.D., *Forest Labs, Inc. v. Cobalt Labs., Inc*., D. Del. C.A. No. 08-00021-LPS, D.I. 224, ¶ 14.[4] In short, Forest itself has equated the method for which Namenda XR is indicated ("treatment of moderate to severe dementia of the Alzheimer's type") with the method to which claim 12 of the patent in suit is directed ("treatment of . . . Alzheimer's disease"). As such, this is most certainly not an "off label" use case. Accordingly, the Complaint more than plausibly pleads that Forest actively induces at least the method of claim 12.[5]

E. Plaintiffs Have Properly Pleaded Contributory Infringement Under 35 U.S.C. § 271(c).

Under 35 U.S.C. § 271(c), a patentee must demonstrate that an alleged contributory infringer has sold, offered to sell or imported into the United States a component of an infringing product "knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use." Courts have held that a complaint states a facially plausible claim of contributory infringement where it alleges that defendant: "(1) had knowledge of the patent; (2) sold products especially made for infringing use; (3) had knowledge of the infringing use; (4) sold products with no substantial non-infringing use; and (5) directly infringed." *Bel*

[4] As a matter of public record, the Court may take judicial notice of the foregoing document and consider it on the present motion, without converting the instant motion to a motion for summary judgment pursuant to Rule 56. *See supra,* note 2.

[5] While there is no requirement that the Complaint identify which claims are asserted, Plaintiffs reserve their right to assert, at the appropriate time, that Forest actively induces and contributes to infringement of independent claim 7 of the patent in suit. After a full and fair exchange of the relevant documents has occurred, Teva and Mayne will address the proper construction of the language in the preamble of claim 7 "[a] method for the therapeutic or prophylactic treatment of pain related to wind-up," and potentially bring forward evidence that Forest knows that most Alzheimer's Disease patients (the vast majority of whom are over age 65, *see* D.I. 9-2, Diagnostic and Statistical Manual of Mental Disorders, 4th Ed., at p. 156) experience agitation and irritability caused by pain, that persons in this group are particularly susceptible to wind-up, and that Forest intends that this condition will be treated with Namenda XR.

Fuse, Inc., 2014 U.S. Dist LEXIS 81954, at *19; see also *Walker Digital*, 852 F. Supp. 2d at 566; *Versata Software, Inc. v. Callidus Software, Inc.,* 944 F. Supp. 2d 357, 363 (D. Del. 2013) (allowing contributory infringement claims to proceed).

The Complaint states a claim for contributory infringement by Forest. With respect to whether Forest had the requisite knowledge of the patent in suit, and intent to contribute to infringement, the Complaint states as follows:

> 28. Defendant has offered for sale and sold Namenda XR® for use in practicing the patented methods claimed in the '000 patent, which use constitutes a material part of the claimed inventions.
>
> 29. On information and belief, Defendant has offered for sale and sold Namenda XR® ***knowing that Namenda XR® is especially made or adapted for use in infringing the '000 patent,*** and that Namenda XR® is ***not a staple article or commodity of commerce suitable for substantial noninfringing use***.
>
> 30. On information and belief, ***Defendant's customers have directly infringed and continue to infringe*** the '000 patent by using Namenda XR® purchased from Defendant to treat medical conditions, including Alzheimer's Disease.
>
> 31. Defendant has contributorily infringed and is continuing to contributorily infringe under 35 U.S.C. § 271(c) the '000 patent.
>
> 32. Defendant's actions constitute ***knowing and willful infringement*** of the '000 patent.

D.I. 1, Complaint (emphasis added). Similar allegations have repeatedly been found sufficient by courts within the Third Circuit and elsewhere. *See e.g., Walker Digital,* 852 F. Supp. 2d at 563; *Bel Fuse, Inc.*, 2014 U.S. Dist LEXIS 81954, at *19; *Versata Software, Inc.,* 944 F. Supp. 2d at 363 (allowing contributory infringement claims to proceed).

Notably, Forest's Motion fails to even address the foregoing factors, apparently relying on its erroneous request that the Court embrace its proposed revision of the claims to require

"treating wind-up." Because the Complaint adequately pleads contributory infringement, Forest's Motion should be denied.

F. The Case Law Cited by Forest Does Not Support Dismissal.

Forest asserts that the Federal Circuit's decisions in *Warner-Lambert Co.,* 316 F.3d 1348 (Fed. Cir. 2003) and *Allergan, Inc.*, 324 F.3d 1322 (Fed. Cir. 2003) support dismissal. However, both of those cases were decided at the *summary judgment* stage, after the parties had the opportunity to develop a full record and the Court had conducted claim construction. As such, those cases support providing Plaintiffs the same opportunity here.

Forest also relies on *Bayer Schering Pharma AG v. Lupin Ltd.,* 676 F.3d 1316 (Fed. Cir. 2012). Though *Bayer* was decided at the pleadings stage, Forest's Motion also fails to find support therein, because unlike in *Bayer*, here, there is no inconsistency between the methods of use claimed in the '000 patent and the methods of use indicated in the label for Namenda XR. For example, as discussed above, claim 12 is directed to a method of treating Alzheimer's Disease, which is the very same indication instructed on the label for Namenda XR.

Moreover, in *Bayer, Warner-Lambert* and *Allergan,* the defendant had committed only an *artificial* act of infringement -- the filing of an ANDA -- and there was no dispute as to the key terms in the patent.[6] In an ANDA case, "the ANDA must be judged on its face for what an accused infringer seeks the FDA's approval to do." *Warner-Lambert,* 316 F.3d at 1364. By contrast, where, as here, Forest is actively marketing the accused *approved* drug, its label is not dispositive as to inducement of infringement. *See e.g., Novartis Pharms.,* U.S. Dist. LEXIS 176445, at *9-10 (distinguishing *Bayer*); *see also Genentech, Inc. v. Trs. Of the Univ. of Pa.,* 871

[6] In all of these cases, only indirect (not direct) infringement was asserted, and such infringement was asserted solely under § 271(e)(2). In contrast, the Complaint here pleads directed infringement under § 271(a) and (g) (Count I), inducement of infringement under § 271(b) (Count II) and contributory infringement under § 271(c) (Count III).

F. Supp. 2d. 963, 977-78 (N.D. Cal. 2012) (refusing to dismiss inducement claim and noting that evidence of active steps, such as advertising or instructions, may be relevant and that a Court "need not find that the drug label teaches infringement in every instance"). Moreover, "the FDA does not prohibit doctors from prescribing a drug for an unapproved or off-label use, and it does not prohibit patients from using a drug for an unapproved or off-label use." *Allergan*, 324 F.3d at 1323, note 1 (citing *Warner-Lambert*, 317 F.3d at 1356). Indeed, Forest admits that "a doctor 'may prescribe an approved drug for any use consistent with acceptable medical practice." D.I. 14, at note 1. Thus, even if the Court were to prematurely embrace Forest's interpretation of the claims the '000 patent, Plaintiffs would still be entitled to discovery as to how Forest markets Namenda XR and its knowledge and intent that such marketing will result in infringement of the '000 patent.

Finally, as held in *Los Angeles Biomedical Research Institute v. Eli Lilly & Co*., Civil Action No. 13-8567 (C.D. Cal. May 12, 2014), which is attached as Exhibit 1 to Forest's Motion, the mere absence of a patent claim term in the accused drug's label is not dispositive, particularly where the claimed method will result from following the label's instructions. D.I. 14-1, p. 6. Though Forest's Motion attempts to distinguish *L.A. Biomedical,* it in fact supports sustaining Plaintiffs' Complaint. As in *L.A. Biomedical,* Forest was indisputably aware of the '000 Patent when it developed its accused product and label. *See* Exh. B, '009 patent, cover page. Moreover, as in L*.A. Biomedical*, infringement of one or more claims of the '000 patent will result when Namenda XR is used by doctors as directed by Forest. D.I. 1, Complaint at ¶ 22. As in *L.A. Biomedical,* Forest's Motion to Dismiss should be denied.

VI. CONCLUSION

Forest's Motion should be denied. Forest's argument improperly asks the Court to rewrite the claims and draw adverse factual inferences. Instead, all interferences must be drawn in Plaintiffs' favor, and all facts in the Complaint must accepted as true. Applying the appropriate standards, the Complaint properly pleads direct and indirect infringement under the Federal Rules of Civil Procedure.

In the alternative, in the event the Court finds any of Counts I, II or III of the Complaint deficient in any respect, Plaintiffs respectfully request leave to file a first amended complaint, to cure any such deficiencies. *See* Fed. R. Civ. P. 15 ("the court should freely give leave when justice so requires").

Respectfully submitted,

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Dated: June 30, 2014
1157624 / 40539

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on June 30, 2014, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on June 30, 2014, the attached document was electronically mailed to the following person(s)

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